DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

M32051

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-10

November 22, 1999

Barbara A. Spears, Owner
Lee N. Spears & Sons Seafood
4193 Spring Creek Highway
Crawfordville, Florida 32327

Dear Mrs. Spears:

We completed an inspection of your crabmeat processing plant on July 29, 1999 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123) and the Good Manufacturing Practice (GMP) regulations for food (21 CFR Part 110). These deviations cause your cooked ready-to-eat crabmeat products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find the Act and these regulations through links in FDA's home page at www.fda.gov.

The deviations from the Seafood HACCP regulations are as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for your cooked stone crab claws to control the food safety hazard of pathogen growth and toxin formation. This deviation was previously brought to your attention in our letter of August 21, 1998.

You must have monitoring records which document the actual values and observations obtained during monitoring, in order to comply with 21 CFR 123.6(c)(7). However, you do not have monitoring records to document time and temperature observations for the cooking, packing and storage critical control points listed in your HACCP plan to control the food safety hazard of pathogen growth and toxin formation in your cooked ready-to-eat crabmeat products.

You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). However, your firm is not monitoring plant water safety, cleanliness of food contact sufaces, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection from

adulterants, proper labeling, storage and use of toxic compounds, control of employee health conditions, and exclusion of pests with sufficient frequency to ensure control. This deviation was previously brought to your attention in our letter of August 21, 1998.

You must have sanitation control records that document the monitoring and correction of sanitation conditions, in order to comply with 21 CFR 123.11(c). However, sanitation control records are not being maintained by your firm. This deviation was previously brought to your attention in our letter of August 21, 1998.

In addition, our investigator observed and documented numerous insanitary conditions and practices during the inspection that are conducive to microbiological contamination of your cooked ready-to-eat crabmeat products, for example, time and temperature abuse during processing and storage, cooked crabs in direct contact with the floor, insanitary equipment, poor employee practices, structural defects, live and dead insects inside and outside the facility, and live animals (three cats) inside the receiving and loading area. Similar observations were previously brought to your attention in our letter of August 21, 1998. We consider these observations to be serious GMP deviations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your cooked ready-to-eat crabmeat products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plan for cooked crab claws, HACCP plan monitoring records, sanitation control records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP regulations and the GMP regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

Douglas D. Tolen
Director, Florida District